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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,780	08/28/2001	Michael O'Connor	650.0002.CON	3969

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,780	O'CONNOR, MICHAEL	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the* "Sequence listing" and in the text of the description and ***claims*** whenever described. For example, the appropriate SEQ ID NO must be recited in claim 4. It is suggested that amending claim 4 to recite the position numbers of the respective SEQ ID NOs should obviate this requirement. See MPEP 2422 & 2431. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Note that failure to respond to both the requirements for sequence compliance and the restriction requirement below will be held as *nonresponsive*, and may result in *abandonment* of this application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 & 4-8, drawn to methods for detecting the agent for TSE comprising reacting a sample with an antibody raised against SEQ ID NO: 1, or fragments thereof, and kits thereof, classified in class 435, subclass 7.21.

II. Claims 1 & 4-8, drawn to methods for detecting the agent for TSE comprising reacting a sample with an antibody raised against SEQ ID NO: 2, or fragments thereof, and kits thereof, classified in class 435, subclass 7.21.

III. Claims 1 & 4-8, drawn to methods for detecting the agent for TSE comprising reacting a sample with an antibody raised against SEQ ID NO: 3, or fragments thereof, and kits thereof, classified in class 435, subclass 7.21.

IV. Claims 1 & 4-8, drawn to methods for detecting the agent for TSE comprising reacting a sample with an antibody raised against SEQ ID NO: 4, or fragments thereof, and kits thereof, classified in class 435, subclass 7.21.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups I-IV are directed to methods for detecting the agent for TSE comprising reacting a sample with an antibody raised against unique polypeptides that are physically and functionally distinct, as illustrated by the unique SEQ ID NOs that define each epitope from which each distinct antibody molecule is produced; thereby, requiring different assay and search considerations.

It is pointed out that there is a proper distinction between these groups, since each product required in each of the different method groups is not required in order for the other methods to exist. Thereby, these groups are distinct and separable for the reasons stated.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as illustrated by the different SEQ ID NOs recited, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider each of the separable groups with their divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined to a single SEQ ID NO even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Robert C. Hayes, Ph.D.
June 25, 2004
pab-5y,
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